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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,271	09/03/2002	Thomas Niehr	F-7322	5161

28107 7590 11/30/2004

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EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,271	NIEHR ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This final office action is in response to the amendment received on 09/20/2004

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, line 5; applicant added the limitation "for a time period sufficient". The disclosure does not teach any time period with regard the starting temperature of sterilization. The same applies to claim 15, line 4.

Claim Objections

3. Claims 1 and 22 are objected to because of the following informalities:

In claim 1, line 7; the word "produced" should be replaced with "produce".

Claim 22 depends on canceled claim 22. In examining claim 22, it is assumed that such a claim depends on claim 15. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-12 and 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vokins et al (U.S.P.N. 5,178,841) in view of Palaniappan et al (U.S.P.N. 6,120,730) and further in view of Dronet (FR 2666299) and Reinecke (DE 3339930).

With respect to claims 1 and 15, the Vokins reference teaches a generic method for sterilizing all different types of containers (col.4) including plastic ones. The

containers are advanced the containers periodically (periodically is equivalent to the predetermined time interval between indexing movements along the conveyor system in col.3, lines 22-25). The hydrogen peroxide aerosol (fine spray droplets of hydrogen peroxide is equivalent to the definition of an aerosol in col.2, lines 50-53) is heated to a starting temperature by heated sterile air (col.4, lines 37-40) such that a condensation film is formed on the inner surfaces of the containers (in col.4, lines 28-30, the reference shows the presence of hydrogen peroxide droplets on the inner surfaces of the containers. Those droplets are equivalent to the layer of condensation). Then sterile air heated to a higher temperature than the starting temperature of the peroxide aerosol is blown into the containers to evaporate the condensate (col.4, lines 44). The Vokins reference discloses a starting temperature and an activation temperature that are higher than the recited temperatures (col.4, lines 39-43) such that the method of the Vokins reference intrinsically applies the sterile air over a period of time whether it involves heating the hydrogen peroxide or drying the containers. In addition, the Vokins reference mixes the peroxide aerosol with the heated air then applies the mixture inside containers (col.4, lines 1-18). The use of the heated air is to vaporize or dissipates (scatter) the aerosol before it is applied to the inner surfaces of containers. However, the Vokins reference fails to disclose the following: sterilizing a temperature-sensitive plastic containers, a starting temperature range, an activation temperature range applied for a time period sufficient to keep interior walls of the bottles at the permissible temperature or less and to further apply sterile air to the containers. The Palaniappan reference teaches sterilizing plastic bottles using hydrogen peroxide gas (abstract, lines

1-12). In addition, the Palaniappan reference teaches the concept of repeating blowing heated sterile air into plastic bottles (34, 36, and col.5, lines 52-54) such that it is intrinsic to the method of the Palaniappan reference to apply sterile air for a sufficient time and temperature that do not affect the integrity of the interior walls of the heat sensitive plastic containers. Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Vokins reference to include plastic bottles as taught by the Palaniappan reference in order to sterilize various types of containers (Palaniappan et al, abstract, lines 11-13).

The Palaniappan reference fails to teach a value range for the starting temperature and the activation temperature. The Dronet reference, which is in the art of sterilizing food containers, teaches heating the aerosol to a temperature of about 80 degree Celsius (the starting temperature). See the use/advantages section, lines 3-4. The Dronet reference is considered by the examiner to provide a generic method for sterilizing all different types of containers (col.4) including plastic ones. Thus, it would have been obvious to one having ordinary skill in the art to modify the method of the Vokins reference by heating the sterile air to a temperature of about 80 degree Celsius as disclosed by the Dronet reference since such a temperature is the optimum temperature for hydrogen peroxide sterilization (use/advantage, lines 3-4).

The Dronet reference fails to teach the activation temperature. The Reinecke reference, which is in the art of sterilizing plastic containers, teaches heating sterile air to a temperature range of 120 to 140 degree Celsius (abstract, lines 9-10). Therefore, it would have been obvious to one having ordinary skill in the art to modify the method of

the Vokins reference to include heating the sterile air to about 120 degree Celsius as taught in the Reinecke reference in order to insure that all of the hydrogen peroxide has been removed from the inner surfaces of the plastic bottles.

In considering the Dronet reference, the Vokins reference and the Reinecke reference, it is obvious that such a temperature range from 80 to 120 degree Celsius is wider than each reference teaches. For example, the Vokins reference discloses a temperature of 108 Degree Celsius, the Dronet reference teaches a temperature of 80 degree Celsius and the Reinecke reference teaches a temperature of 120 degree Celsius such that modifying a wide range of 80 to 120 degree Celsius to a smaller range of 60 to 90 degree Celsius is a matter of routine variable optimization that is within the scope of the artisan.

With respect to claims 2 and 4, the aerosol (aerosol is equivalent to fog) is produced by means (1) at ambient temperature since the Vokins reference heats the peroxide aerosol to a first temperature (5 and the unlabeled arrows in figure 1) after it is produced. The incoming air is heated first then mixed with the aerosol as in figure 1, such that the temperature of the sterile air after being heated but before is mixed with the aerosol is higher (an activation temperature) than its temperature after mixing with the peroxide aerosol (sterilization starting temperature).

With respect to claim 3, the Dronet reference teaches heating the aerosol to a temperature of about 80 degree Celsius (use/advantages, lines 3-4).

With respect to claims 5, the Palaniappan reference method teaches applying the hydrogen peroxide and air separately (28 and 34) such that hydrogen peroxide is

introduced into plastic bottles in two separate and consecutive steps (63 and 64) with pausing time intervals in between such steps (col.4, lines 38-45). In addition, sterile air is blown inside plastic bottles in two separate steps (two separate nozzles113). The Palaniappan reference fails to teach heating the hydrogen peroxide to the activation temperature. The Reinecke reference, which is in the art of sterilizing plastic containers by atomizing hydrogen peroxide, teaches heating sterile air to a temperature range of 120 to 140 degree Celsius (abstract, lines 9-10). Therefore, it would have been obvious to one having ordinary skill in the art to modify the method of the Palaniappan reference to include heating the sterile air to about 120 degree Celsius as taught in the Reinecke reference in order to insure that all of the hydrogen peroxide has been removed from the inner surfaces of the plastic bottles.

With respect to claims 6-8,10-12 and 14, the Palaniappan reference method teaches that sterile air is blown inside plastic bottles in two separate steps (two separate nozzles113). Further, the concept of multiple and separate application of sterile air is taught in the Palaniappan reference (34, 36, and col.5, lines 52-54). The Palaniappan reference discloses a velocity value for the blown sterile air (col.9, bottom of table one) such that velocity and flow rate are intrinsically related to each other. Adjusting the velocity of the sterile air intrinsically results in changing the value of the flow rate such that the desired velocity of the sterile air depends on the type of the containers to be sterilized. For example, big containers require more air for drying purposes versus small containers. The Palaniappan reference discloses a volume flow rate for hydrogen peroxide (col.5, lines 37-38) such that volume and flow rate are intrinsically related to

each other. Adjusting the flow rate of the peroxide intrinsically results in changing the value of the volume such that the desired volume for the peroxide depends on the degree of sterilization intended and on the size of containers to be treated.

With respect to claims 9, 24, and 28, the Reinecke reference teaches heating sterile air to a temperature of 110 degree Celsius (abstract, lines 4-5).

The limitations for claims 16-19, 25-27, and 29 have previously been addressed above with respect to claims 5-8, 10-12, and 14.

The limitations for claims 20 and 23 have previously been addressed above with respect to claims 2 and 4.

With respect to claim 22, the Dronet reference teaches heating the aerosol to a temperature of about 80 degree Celsius (use/advantages, lines 3-4).

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vokins et al (U.S.P.N. 5,178,841) in view of Palaniappan et al (U.S.P.N. 6,120,730) and further in view of Dronet (FR 2666299), Reinecke (DE 3339930) and Hatanaka et al (U.S.P.N. 4,797,255).

With respect to claim 13, the Vokins, the Palaniappan, the Dronet and the Reinecke references all fail to disclose a time range for blowing sterile air. The Hatanaka reference teaches a time range of 5 seconds and less of blowing sterile air for removal of deposited hydrogen peroxide (col.8, lines 5-7). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of the Vokins reference by blowing sterile air for 5 seconds or less as disclosed in the Hatanaka

reference for the complete removal of the hydrogen peroxide condensate (col.8, lines 3-7).

9. Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vokins et al (U.S.P.N. 5,178,841) in view of Palaniappan et al (U.S.P.N. 6,120,730) and further in view of Dronet (FR 2666299), Reinecke (DE 3339930) and Zaelke (U.S.P.N. 4,478,781).

With respect to claims 30-31, the Vokins, the Palaniappan, the Dronet and the Reinecke references all fail to disclose a permissible temperature of 55 degree Celsius or less. The Zaelke reference, which is in the art of treating plastic containers, teaches applying heated air to a temperature not less than 103 degree Fahrenheit, which is equivalent to 39.4 degree Celsius (col.5, lines 17-19). Applying air at a temperature not less than 39.4 degree Celsius would intrinsically maintain the temperature of the interior walls of the plastic containers at temperature of less than 55 degree Celsius. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the temperature of the sterile air within the container of the Vokins reference to a temperature not less than 39.4 degree Celsius as taught by the Zaelke reference in order to obtain a treated plastic container with unaltered structural integrity (col.1, lines 20-21).

Response to Arguments

10. Applicant's arguments filed 09/20/2004 have been fully considered but they are not persuasive.

On page 15 of the Remarks section, applicant argues that, "These steps differ appreciably from the process steps of the method of the application and are not suitable for anticipating the invention or making it obvious." The examiner disagrees. The Vokins reference teaches a generic method for sterilizing all different types of containers (col.4) including plastic ones such that the containers are advanced the containers periodically Then the hydrogen peroxide aerosol (fine spray droplets of hydrogen peroxide is equivalent to the definition of an aerosol in col.2, lines 50-53) is heated to a starting temperature by heated sterile air (col.4, lines 37-40) such that a condensation film is formed on the inner surfaces of the containers (in col.4, lines 28-30, the reference shows the presence of hydrogen peroxide droplets on the inner surfaces of the containers. Those droplets are equivalent to the layer of condensation). Then sterile air heated to a higher temperature than the starting temperature of the peroxide aerosol is blown into the containers to evaporate the condensate (col.4, lines 44). The Vokins reference discloses a starting temperature and an activation temperature that are higher than the recited temperatures (col.4, lines 39-43) in the instant claims such that the method of the Vokins reference intrinsically applies the sterile air over a period of time whether it involves heating the hydrogen peroxide or drying the containers.

On page 15 of the Remarks section, applicant argues that, "Clearly the Vokins reference teaches temperatures higher than those of the present invention which would not be conducive to the goal of preventing damage to the temperature sensitive plastic materials of the bottles." The Vokins reference is combined with the Dronet reference and the Reinecke reference to show that such temperatures are known in the art of

treating plastic bottles such that maintaining the integrity of such containers is an intrinsic goal of such references. For example, in considering the Dronet reference, the Vokins reference and the Reinecke reference, it is obvious that such a temperature range from 80 to 120 degree Celsius is wider than each reference teaches alone. The Vokins reference discloses a temperature of 108 Degree Celsius, the Dronet reference teaches a temperature of 80 degree Celsius and the Reinecke reference teaches a temperature of 120 degree Celsius such that modifying a wide range of 80 to 120 degree Celsius to a smaller range of 60 to 90 degree Celsius is a matter of routine variable optimization that is within the scope of the artisan.

On page 16 of the Remarks section, applicant argues that, "While Hatanaka is cited for teaching a time range of 5 seconds, this range is applicable only to the conditions of the Hatanaka process and would not be construed applicable to other conditions." The Hatanaka reference is only combined to show that the concept of blowing sterile air over a relatively short period of time is known in the art of treating containers and is not related to the recited temperatures in the instant claims. Such temperatures are disclosed in the Dronet and the Reinecke references, both of which are in the art to treating containers. One skilled in the art would recognize that after reading the Vokins reference, the Dronet reference, the Reinecke reference and the Tanaka reference that a wide temperature range is disclosed in the art of treating plastic containers such that optimizing the sterile air blowing time is a matter of routine experimentation that depends on the degree of dryness preferred which is a function of the sterile air temperature used.

On page 16 of the Remarks section, applicant argues that, "The temperature relationships and course of the steps of the process are completely different in the case of this reference, even if condensate is formed at the surface of the container, which is to be sterilized." Again, The Hatanaka reference is only combined to show that the concept of blowing sterile air over a relatively short period of time is known in the art of treating containers. The Hatanaka reference is not combined for the temperature relationships or the course of the steps of the process or for the condensate formation on the surface of the container. Such limitations were addressed in the Vokins reference and the Dronet and the Reinecke references.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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